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Excluding Substandard Canned Pineapple From The United States

Food and Drug Administration

Department of Health, Education, and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

MWD-75-40

MARCH 3,1975

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-179440

The Honorable Daniel K. Inouye
United States Senate

Dear Senator Inouye:

Pursuant to your request of August 6, 1973, and discussions with your office, this is our report on the Food and Drug Administration's efforts to exclude substandard canned pineapple from the United States.

The Administration is part of the Department of Health, Education, and Welfare. We obtained written comments from the Department on matters in the report.

We do not plan to distribute this report further unless you agree or publicly announce its contents. In this connection, we want to invite your attention to the fact that this report contains recommendations to the Secretary of Health, Education, and Welfare which are set forth on page 15. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions he has taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report. When we obtain your agreement to release the report, we will make it available to the Secretary and the four Committees for the purpose of setting in motion the requirements of section 236.

Sincerely yours,

Elmer B. Staats

Comptroller General
of the United States

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ABBREVIATIONS

FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic (Act)
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare

COMPTROLLER GENERAL'S
REPORT TO THE
HONORABLE DANIEL K. INOUYE
UNITED STATES SENATE

EXCLUDING SUBSTANDARD CANNED PINEAPPLE FROM THE UNITED STATES

Food and Drug Administration
Department of Health,
Education, and Welfare

D I G E S T

WHY THE REVIEW WAS MADE

Senator Daniel K. Inouye asked GAO to examine the Food and Drug Administration's current efforts to exclude substandard pineapple imports from the United States.

FINDINGS AND CONCLUSIONS

The Food and Drug Administration administers the Federal Food, Drug, and Cosmetic Act, as amended. The act prohibits introducing adulterated or misbranded food into interstate commerce.

Section 401 of the act provides for establishing standards of identity, quality, and fill of container for food products to promote honesty and fair dealings in the interest of consumers.

The Food and Drug Administration has promulgated regulations which establish standards for canned pineapple. Imported canned pineapple found not to comply with the standards is subject to detention. (See p. 1.)

A 1969 Pineapple Growers Association survey of more than 100 samples of canned pineapple showed that about 20 percent were below the Food and Drug Administration's quality standards.

A 1970 survey of canned pineapple from Malaysia, Mexico, and Taiwan by the Food and Drug Administration showed that 16.4 percent and 4.3 percent of the lots sampled from Taiwan and Malaysia, respectively, did not comply with the standards. (See p. 2.)

In January 1972 an independent firm, in conjunction with the Pineapple Growers Association of Hawaii, surveyed canned pineapple from Malaysia, Mexico, Taiwan, and Thailand. More than 50 percent of the 120 samples examined failed to meet quality standards. (See p. 2.)

In fiscal year 1973 the Food and Drug Administration began a survey to determine the sources and incidence of domestic or imported substandard canned pineapple. A similar survey covering only pineapple from Malaysia and Taiwan was undertaken during fiscal year 1974.

Fiscal year 1973 survey of imported and domestic canned pineapple

The 1973 survey plan called for sampling 460 lots of canned pineapple for excess trim, core, or blemish.

The Food and Drug Administration sampled only 408 lots and rejected 40, or about 10 percent, of them as not meeting its quality standards. According to the survey, during fiscal year 1973 Taiwan and Malaysia were the principal sources of imported substandard pineapple. Virtually all canned pineapple examined from other sources, including Hawaii, complied with the Food and Drug Administration's quality standards. (See p. 3.)

Of the 40 lots, 29 were denied entry into the United States, 3 were relabeled as substandard and were allowed entry, and the disposition of the remaining 8 lots varied.

Effectiveness of 1973 survey

The survey plan specified how many cans were to be examined as well as how many cans had to be substandard for a single quality factor to cause the lot to be rejected. (See p. 5.)

For example, under the plan, a lot would be rejected if 3, or 25 percent, of 12 cans were substandard for the same quality factor but would possibly not be rejected if 6, or 50 percent, of the cans were substandard for a combination of quality factors.

It seems inconsistent to GAO to reject a lot when 25 percent of a sample is substandard for the same quality factor but possibly accept a lot when 50 percent of the sample is substandard for a combination of several quality factors. (See p. 7.)

Deviations from sampling plan

The participating Food and Drug Administration district offices did not follow the sampling plan.

Although the plan called for sampling 460 lots of canned pineapple, district offices sampled only 408 lots.

Because districts did not comply with the sampling plan, survey results could not be projected to all canned pineapple imported into the United States during fiscal year 1973. (See p. 7.)

Also, district offices did not, in all cases, collect samples randomly throughout the lot so that the various can codes in the lot would be included or considered in the sample collection. (See p. 7.)

Standards not uniformly applied

The survey plan required Food and Drug Administration headquarters verification whenever district offices found a lot of canned pineapple to be substandard. Its district offices submitted samples from 54 lots to headquarters for verification.

Headquarters disagreed with the district offices' findings for 14, or 26 percent, of the 54 lots. (See p. 8.)

The discrepancy between the headquarters and district analyses was attributed to inexperienced district personnel and the varying degree to which each required compliance with the Food and Drug Administration's quality standards. (See p. 9.)

Fiscal year 1974 survey of imported canned pineapple

The fiscal year 1974 survey guidelines were basically the same as those issued for the fiscal year 1973 survey except that the survey was

limited to pineapple from Taiwan and Malaysia. The Food and Drug Administration sampled 198 of the 200 lots required to be sampled by the plan and rejected 37, or about 19 percent, of the lots. (See p. 10.)

As of September 1974, 16 of 37 lots had been relabeled as substandard and were allowed to enter the United States, 7 were denied entry, and disposition of the remaining 14 lots was still pending. (See p. 11.)

As in the case of the 1973 survey, lots were deemed substandard on the basis of a specified number of samples not meeting the same quality factor rather than a combination of quality factors. Because an additional quality factor (drained weight) was considered, a lot could be acceptable when as many as 67 percent of the samples were substandard for a combination of quality factors. (See p. 11.)

In fiscal year 1974 Food and Drug Administration headquarters disagreed with the district offices' findings for 15 percent, or 6, of the lots from which samples were submitted for verification. (See p. 11.)

Sampling plan not strictly adhered to

In sampling 198 lots, 12 of the 14 participating districts deviated from the sampling plan. Although not all samples were collected in accordance with the plan, officials believed the results were representative of canned pineapple imports from Malaysia and Taiwan because the survey involved samples from only two countries and the total number of samples collected substantially agreed with the number required. (See p. 13.)

Fiscal year 1975 survey not planned

In September 1974 a Food and Drug Administration official said that, because of limited manpower, the Administration did not plan to conduct a fiscal year 1975 survey of imported canned pineapple. (See p. 13.)

Although recent surveys showed that significant amounts of canned pineapple from Taiwan and Malaysia were substandard, the Food and Drug Administration's regulatory action has been limited to those lots included in its survey samples. As a result, only substandard lots included in the survey were refused entry into the United States.

However, it does not appear that the surveys achieved their purpose of significantly reducing entry of substandard products. (See p. 14.)

The Food and Drug Administration should provide for special inspection of pineapple imported from Taiwan and Malaysia to protect the interest of consumers as provided by the Federal Food, Drug, and Cosmetic Act. To make the best use of its limited resources, the Food and Drug Administration's inspection activities could focus on the specific processors found to be most responsible for substandard pineapple. (See p. 14.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

The Secretary of HEW should direct the Commissioner of the Food and Drug Administration to

--provide for special inspection of imported canned pineapple from Malaysia and Taiwan,

--evaluate the appropriateness of accepting lots which may be substandard for a combination of quality factors, and

--provide additional training and guidance to inexperienced district office personnel who participate in inspections to insure that quality standards are properly applied. (See p. 15.)

AGENCY ACTIONS AND UNRESOLVED ISSUES

HEW stated that the Food and Drug Administration could not conduct a special inspection of imported pineapple at the present time because of resource limits but that it would inspect imported canned pineapple as part of its regular compliance program to identify and take corrective action against any product not complying with Food and Drug Administration food standards.

Also, the Food and Drug Administration will continue to evaluate the results of its canned pineapple survey programs for fiscal years 1973 and 1974 and will give appropriate consideration to undertaking additional programed activity in the future.

HEW also said that the Food and Drug Administration would evaluate the appropriateness of accepting lots which may be substandard for a combination of quality factors.

HEW agreed that the Food and Drug Administration should provide additional training and guidance to inexperienced district office personnel who participate in inspections to insure that quality standards are properly applied, and HEW advised GAO that steps have been taken in this regard. (See p. 15.)

CHAPTER 1

INTRODUCTION

By letter dated August 6, 1973, Senator Daniel K. Inouye asked us to look into the Food and Drug Administration's (FDA's) current efforts to exclude substandard pineapple imports from the United States.

FDA'S RESPONSIBILITY TO REGULATE FOOD

FDA, Department of Health, Education, and Welfare (HEW), administers the Federal Food, Drug, and Cosmetic (FD&C) Act, as amended (21 U.S.C. 301), which prohibits introducing adulterated or misbranded food into interstate commerce.

Section 401 of the FD&C Act provides for establishing standards of identity, quality, and fill of container for food products to promote honesty and fair dealing in the interest of consumers. FDA has promulgated regulations (21 C.F.R. 27.50, 27.51, and 27.52) establishing such standards for canned pineapple. The regulations, which apply to imported as well as domestic canned pineapple, specify limits for thickness, width, and weight of pineapple pieces and the amount of core material and number of blemished pieces allowed for a given weight of drained fruit.

For example:

--In canned pineapple chunks, not more than 15 percent of the drained weight may consist of pieces weighing less than 3/16 of an ounce.

--In canned pineapple slices and half slices, not more than 7-1/2 percent of the units in a container may be excessively trimmed.

--In canned pineapple slices, half slices, broken slices, spears, chunks, cubes, and tidbits, not more than 12-1/2 percent of the units in any container may be blemished. Blemishes include deep fruit eyes, bruises, and other abnormalities exceeding 1/16 inch in the longest dimension on the exposed surface of the unit.

--In all forms of canned pineapple, not more than 1.1 ounces of core may be contained in 1 pound of drained fruit.

Imported canned pineapple not complying with the standards is subject to detention under authority of the Department of the Treasury's Bureau of Customs. When a product is detained, FDA, through the Bureau of Customs, issues to the importer a "Notice of Detention and Hearing." If the importer disagrees with the basis for the detention it may request

an informal hearing before the director of the FDA district. If the findings are sustained during the hearing the importer must either (1) destroy the product, (2) reexport the product, or (3) recondition the product or relabel it as substandard. The importer generally has 60 days from the date of the detention notice to take action.

When the importer chooses to recondition the substandard pineapple, it must notify FDA when such action will take place so that FDA may monitor the reconditioning process. Reconditioned products, after reinspection and approval by FDA, are released for entry into the country. If a reconditioned product cannot meet FDA standards, it must be destroyed or removed from the country.

When the importer relabels the substandard pineapple, the new label must indicate that the product fails to comply. For example, the label could bear the statement "Below Standard in Quality Good Food-Not High Grade" or could include one of the following notations: "Excessively trimmed," "Blemished," "Contains blemished pieces," "Poorly cored," "Excessive core," or "Contains excess liquid."

SURVEYS OF CANNED PINEAPPLE

During 1969 to 1972 FDA and the Pineapple Growers Association of Hawaii separately surveyed imported canned pineapple to determine whether the pineapple complied with FDA quality standards. The principal sources of canned pineapple entering the continental United States are Hawaii, Malaysia, Mexico, the Philippines, Taiwan, and Thailand.

In 1969 the Pineapple Growers Association of Hawaii surveyed more than 100 samples of canned pineapple and found that about 20 percent did not conform to FDA's quality standards. In 1970 FDA surveyed pineapple imported from Malaysia, Mexico, and Taiwan and found that 16.4 percent and 4.3 percent of the lots sampled from Taiwan and Malaysia, respectively, did not comply with FDA quality standards. Samples from Mexico did comply.

In January 1972 an independent firm, in conjunction with the Pineapple Growers Association of Hawaii, surveyed canned pineapple from Malaysia, Mexico, Taiwan, and Thailand. More than 50 percent of the 120 samples examined failed to meet quality standards. About 68 percent of the samples from Malaysia, 50 percent from Thailand, 44 percent from Taiwan, and 38 percent from Mexico were substandard.

As a result of the findings in the preceding surveys, FDA in October 1972 initiated a survey (fiscal year 1973 survey) to determine the sources and incidence of domestic or imported substandard canned pineapple and to take regulatory action against such products. FDA allotted about 5 man-years of field time for the fiscal year 1973 survey. An FDA fiscal year 1974 survey, for which about 1-1/3 man-years were allotted, covered pineapple from Malaysia and Taiwan only.

CHAPTER 2

FISCAL YEAR 1973 SURVEY OF IMPORTED AND DOMESTIC CANNED PINEAPPLE

In its fiscal year 1973 canned-pineapple survey, FDA examined 408 lots[1] of imported and domestic canned pineapple. On the basis of its examinations, FDA rejected 40, or about 10 percent, of the lots as not meeting FDA quality standards. Taiwan and Malaysia were the principal sources of substandard pineapple. Virtually all canned pineapple examined from other sources, including Hawaii, complied with FDA quality standards.

However, FDA deviated from its statistical sampling plan, thus invalidating the statistical projectability of the results to all canned pineapple imported into the United States during fiscal year 1973. Also, inherent weaknesses in the design of the plan and guidelines for its implementation limited the survey's effectiveness.

SAMPLING PLAN

As part of its 1973 survey, FDA devised a statistical sampling plan which required FDA district offices to collect samples from 460 lots and analyze them for compliance with FDA quality standards. This plan was based on the volume of domestic and foreign canned pineapple which entered the continental United States through nine FDA district offices.

Data developed by the Department of Commerce shows that for calendar year 1972 about 5.5 million cases of canned pineapple were imported into the United States. The 3 largest sources were the Philippines with about 2.3 million cases, Taiwan with about 1.7 million cases, and Malaysia with about 600,000 cases.

The following table shows the sampling plan for each district.

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[1] A lot is a nonfixed number of the same size cans of a particular product, such as sliced or crushed pineapple similarly packed in water,, pineapple juice, heavy syrup, or other substances.

District	Sources of Canned Pineapple Number of lots to be sampled Taiwan	Malay-sia	Mexico	Philip-pines	Other countries (note a)	Hawaii	Total
Atlanta	25	-	14	-	25	-	64
Baltimore	21	-	8	-	40	-	69
Dallas	8	-	33	-	-	-	41
Los Angeles	22	10	-	5	-	8	45
New Orleans	7	-	5	-	-	-	12
New York	25	-	-	-	-	-	25
Philadelphia	7	-	5	-	5	-	17
San Francisco	20	30	-	5	-	8	63
Seattle	65	25	-	20	-	14	124
Total	200	65	65	30	70	30	460

[a]Includes Thailand, South Africa, Japan, and Australia.

Although the plan called for sampling 460 lots of imported and domestic canned pineapple, FDA sampled only 408 lots. Of these, it rejected 40 lots as not meeting its quality standards. Most of these rejections were because of excess blemishes. Seven additional lots were rejected for reasons other than quality standards, such as improper labeling and leaking or rusty cans.

The following table shows the results of FDA's fiscal year 1973 survey of canned pineapple.

Source	Number of lots sampled	Lots not complying with FDA quality standards Number	Percent
Malaysia	93	16	17
Mexico	60	1	2
Taiwan	196	22	11
Thailand	10	1	10
South Africa	22	-	-
Hawaii	16	-	-
Philippines	9	-	-
Japan	1	-	-
Australia	1	-	-
Total	408	40	10

As shown in the above table, only lots from Malaysia, Taiwan, Thailand, and Mexico failed to comply with FDA quality standards.

Of the 40 lots that failed to meet FDA quality standards, 29 ultimately were denied entry into the United States because they were not brought into compliance with the standards, 3 lots were relabeled as substandard and allowed entry, and disposition of the remaining 8 lots varied. Portions of some of the eight lots were brought into compliance with FDA standards or relabeled as substandard and other portions were destroyed or reexported.

Of the 29 lots denied entry, 11 were from Malaysia and 18 were from Taiwan.

EFFECTIVENESS OF FDA'S SURVEY

The purpose of the 1973 survey was to reduce the amount of domestic or imported substandard canned pineapple marketed in the United States. The 1973 survey plan required that the contents of the sampled cans be examined specifically for excessive trim, core material, and blemish quality factors. If examination revealed an additional problem, that was also to be examined.

The plan specified how many cans were to be examined, as well as how many cans had to be substandard in the same quality factor (trim, core, or blemishes) to cause the lot to be rejected. The size of each sample was statistically determined on the basis of can size and the number of cans in a lot, as shown in the following table.

Number of cans in lot		
Equal to or less than 2.2 lbs. per can	Between 2.2 lbs. and 10 lbs. per can (note a)	District sample size (cans)
4,800 or less	2,400 or less	6
4,801 to 24,000	2,401 to 15,000	12
24,001 to 48,000	15,001 to 24,000	24
48,001 to 84,000	24,001 to 42,000	30
84,001 to 144,000	42,001 to 72,000	48
144,001 to 240,000	72,001 to 120,000	84
over 240,000	over 120,000	120

[a]Pineapple generally is not packed in quantities of 10 pounds or more per can.

The FDA district offices were to use the following statistically derived multiple-stage analytical plan to collect and examine samples. The plan was designed so that the analytical results would be projectable to the entire lot with a 95-percent rate of confidence.

District sample size (cans)	Cans to be examined		Cumulative number of defects required to accept	reject	continue analysis (Stage 2)
6	Stage 1	4	0	2	1
	Stage 2	2	1	2	-
12	Stage 1	5	0	2	1
	Stage 2	7	2	3	-
24	Stage 1	12	1	4	2 or 3
	Stage 2	12	3	4	-
30	Stage 1	15	1	4	2 or 3
	Stage 2	15	4	5	-
48	Stage 1	24	2	5	3 or 4
	Stage 2	24	6	7	-
84	Stage 1	42	3	7	4,5, or 6
	Stage 2	42	9	10	-
120	Stage 1	60	5	9	6,7, or 8
	Stage 2	60	12	13	-

As shown in the above table, from a sample of 12 cans, 5 cans would initially be examined. If none were substandard the lot would be accepted, but if two were substandard for the same quality factor the lot would be rejected. If one of the five cans were substandard seven more cans would be examined. The "reject" number was based on the cumulative number found substandard under stages one and two. Thus, if 2 of the 7 were substandard in the second stage, making a total of 3 substandard of the 12 cans sampled, the lot would be rejected. In all cases the reject number was the number of cans substandard in the same quality factor--not a combination of quality factors. Thus, to reject a lot based on the examination of 12 cans, 3 must be substandard in either trim, core, or blemishes.

Accordingly, although a lot was rejected in cases where 3, or 25 percent, of 12 cans were substandard in the same quality factor, it was possible for a lot to be accepted with 6, or 50 percent, of the 12 samples substandard in a combination of quality factors.

For example, using the same sample of 12 cans, 3 of the 5 cans initially examined could each have been substandard for different quality factors and 3 of the additional 7 cans examined could have been substandard for different quality factors. Thus, 6, or 50 percent, of the 12 sampled cans could have been substandard for a combination of quality factors (2 each for trim, core, or blemishes) and the lot would not have been rejected.

It seems inconsistent to reject a lot for which 25 percent of a sample is substandard in the same factor and possibly accept a lot for which 50 percent of the sample may be substandard in a combination of factors. From the FDA records we examined, we were not able to determine how many imported pineapple lots were substandard in a combination of quality factors and yet were permitted entry into the United States.

DEVIATIONS FROM SAMPLING PLAN

The participating FDA district offices did not follow the sampling plan. Because the district offices did not comply with FDA's sampling plan, the statistical projectability of the survey findings to all canned pineapple imported into the United States during fiscal year 1973 was invalidated.

Although the plan called for sampling 460 lots of canned pineapple, district offices only sampled 408 lots. Some district offices sampled more lots from certain sources than required, some sampled fewer, and others sampled none. For example, the Dallas district office was not to sample any lots from Singapore but sampled 15, and the Atlanta district office was to sample 25 lots from Taiwan but sampled 46. Conversely, the Seattle district office sampled only 36 of the required 65 lots from Taiwan and did not sample any from the Philippines or Hawaii.

In a memorandum dated August 2, 1973, an official of FDA's Bureau of Foods, Division of Mathematics, stated that excessive sampling and examinations performed by district offices during the fiscal year 1973 survey and decisions to accept or reject lots on other than the prescribed sample sizes and procedures invalidated any statistical projections made about the designed plan. Also, according to this official, the projectability of the analytical results at a 95-percent rate of confidence was based, in part, on the assumption that sample cans would be randomly collected from throughout the lot. However, the survey plan did not specify that the sample collection was to be randomly collected throughout the lot.

The district offices did not always collect samples so that the various can codes in the lot were included or considered in the sample collection. Can codes--numbers, letters, or symbols embossed on can lids--represent information concerning the contents of the can, the date it

was processed, the location of the cannery, and additional information deemed necessary by the processor. A lot with several codes could indicate that the pineapple was processed on different dates or at different canneries. In such a case the quality of the pineapple might not be uniform throughout the lot.

Sample collection reports submitted to FDA headquarters indicated that some lots did include cans with different codes but that the samples did not always include the various codes in the lot. For example, in a lot from Malaysia consisting of 240 cases of pineapple tidbits in heavy syrup, the FDA district office reported that only cans with identical codes were sampled from 6 cases even though "numerous" other can codes were present. In such cases it was possible that the samples collected and examined may not have reflected the condition of the entire lot.

STANDARDS NOT UNIFORMLY APPLIED

FDA's survey plan required FDA headquarters verification whenever district offices found a substandard lot. For each such lot the district office was to collect an additional sample to send to FDA headquarters for verification.

The district offices submitted samples from 54 lots to headquarters for verification. Samples from 40 of the lots were confirmed to be substandard in a given quality factor and actions were taken against the lots. Samples from 14, or about 26 percent, of the 54 lots were found to comply with the quality standards, and no actions were taken against the 14 lots.

The following table shows the number of lots from which samples were submitted for headquarters verification, the number and percent of lots confirmed as being substandard, and the number and percent of lots not confirmed as substandard.

District office	Number of lots from which samples were submitted to headquarters	Confirmed as substandard		Not confirmed as substandard	
		Number	Percent	Number	Percent
Atlanta	4	3	75	1	25
Baltimore	0	0	-	0	-
Dallas	0	0	-	0	-
Los Angeles	1	1	100	0	0
New Orleans	1	0	0	1	100
New York	7	7	100	0	0
Philadelphia	1	1	100	0	0
San Francisco	8	5	63	3	37
Seattle	32	23	72	9	28
Total	54	40	74	14	26

We discussed the variances between headquarters and district analyses with a Bureau of Foods official. He pointed out that the district analyses were sometimes performed by inexperienced personnel. He also said that the variances between headquarters and the districts may also be attributed to the varying degrees to which each required compliance with FDA's quality standards.

PINEAPPLE GROWERS ASSOCIATION 1973 SURVEY

In August 1973 the Pineapple Growers Association of Hawaii sampled canned pineapple from Malaysia, Mexico, Taiwan, and Thailand. According to the Association, 34, or about 29 percent, of 118 cans examined failed to meet FDA quality standards. The following table shows the results of the 1973 survey.

Origin	Number of cans sampled	Not in compliance	
		Number	Percent
Malaysia	59	22	37
Mexico	19	2	11
Taiwan	30	7	23
Thailand	10	3	30
Total	118	34	29

CHAPTER 3

FISCAL YEAR 1974 SURVEY OF IMPORTED CANNED PINEAPPLE

In view of the results of its fiscal year 1973 survey, FDA again surveyed imported canned pineapple in fiscal year 1974.

The 1974 survey guidelines were basically the same as those for the 1973 survey, except that the survey was limited to canned pineapple from Taiwan and Malaysia because FDA's 1973 survey data indicated these countries were the principal sources of substandard canned pineapple. In addition, the 1974 survey guidelines specified random collection of samples from throughout the selected lots. The guidelines also encouraged district office supervisors to review the sampling schedule and multiple-stage analytical plan with participating field personnel to insure proper sampling.

FDA examined samples from 198 lots from Taiwan and Malaysia and rejected 37, or about 19 percent, of the lots as not meeting FDA quality standards. (In fiscal year 1973 about 13 percent of the lots sampled from Taiwan and Malaysia were substandard.) Samples from the 198 lots were not always collected in accordance with the plan. However, based on their preliminary analysis of the survey data, FDA officials believed the results would be sufficiently representative of canned pineapple imports from Malaysia and Taiwan.

FDA's statistical sampling plan provided for the collection and analysis of samples from 200 lots of canned pineapple. Besides excess trim, core, and blemish, an additional quality factor was examined--drained weight.

The number of lots to be sampled was based on the volume of canned pineapple imported from Taiwan and Malaysia as reported by the Department of Commerce for calendar year 1972. The distribution among districts is shown in the following table.

Sampling Plan for Imported Canned Pineapple FY 1974

District	Number of lots to be sampled		
	Taiwan	Malaysia	Total
Atlanta	18	4	22
Baltimore	18	9	27
Boston	5	1	6
Chicago	3	0	3
Dallas	1	5	6
Detroit	2	0	2
Los Angeles	6	4	10
Minneapolis	0	2	2
New Orleans	4	0	4
New York	26	4	30
Orlando	12	0	12
Philadelphia	3	0	3
San Francisco	30	19	49
Seattle	20	4	24
Total	148	52	200

SURVEY RESULTS

FDA sampled 198 of the 200 lots of imported canned pineapple required by the plan. One hundred and fifty were from Taiwan and 48 were from Malaysia. FDA found 37 lots to be substandard. Of these, 25 were from Taiwan and 12 were from Malaysia. Substandard pineapple in the 37 lots generally contained excess core or blemishes. Three additional lots were rejected for reasons other than failure to meet quality standards--such as improper labeling.

As of September 1974, 16 of the 37 lots had been relabeled as substandard and allowed entry into the United States, 7 were denied entry, and disposition of the remaining 14 was still pending.

As in the 1973 survey, lots were deemed substandard on the basis of the same quality factor rather than a combination of quality factors. Accordingly, a lot could be acceptable even when as many as 67 percent of the samples were substandard for a combination of quality factors. (See p. 6.)

The district offices found 41 of the 198 lots to be substandard for excess core, trim, or blemishes and 2 for noncompliance with drained weight standards. No headquarters verification was required for pineapple below standard in drained weight, but, of the 41 lots from which samples were submitted to headquarters, 35 were confirmed as substandard

and the appropriate actions were taken. FDA headquarters did not agree with the districts' findings for 6, or about 15 percent, of the samples and no actions were taken against the 6 lots. The following table shows the results of the headquarters analyses of samples submitted by the districts.

District office	Number of lots from which samples were submitted to headquarters	Confirmed as substandard		Not confirmed as substandard	
		Number	Percent	Number	Percent
Baltimore	7	7	100	0	0
Boston	1	1	100	0	0
Dallas	3	2	67	1	33
Los Angeles	1	1	100	0	0
New York	4	4	100	0	0
San Francisco	16	13	81	3	19
Seattle	9	7	78	2	22
Total	41	35	85	6	15

A Bureau of Foods official again attributed the differences between the headquarters and district analyses to inexperienced district personnel and to the varying degree to which each required compliance with FDA's quality standards. (See p. 9.)

SAMPLING PLAN NOT STRICTLY ADHERED TO

Twelve of the 14 participating districts deviated from the sampling plan by collecting too many or too few samples per given source.

The following table shows the number of lots assigned by source and the number and percent of lots sampled.

District office	Taiwan Lots Assigned	Taiwan Lots Sampled	Taiwan Percent	Malaysia Lots Assigned	Malaysia Lots Sampled	Malaysia Percent
Atlanta	18	20	111	4	4	100
Baltimore	18	28	156	9	5	56
Boston	5	6	120	1	0	0
Chicago	3	3	100	0	0	-
Dallas	1	4	400	5	4	80
Detroit	2	1	50	0	0	-
Los Angeles	6	4	67	4	3	75
Minneapolis	0	0	-	2	0	0
New Orleans	4	3	75	0	3	-
New York	26	20	77	4	2	50
Orlando	12	8	67	0	0	-
Philadelphia	3	0	0	0	3	-
San Francisco	30	33	110	19	20	105
Seattle	20	20	100	4	4	100
Total	148	150	101	52	48	92

In September 1974 an official of the Bureau of Foods, Division of Mathematics, told us no final analysis for the 1974 survey had been prepared. However, the Bureau's review of preliminary data indicated that the results were representative of pineapple imports from Malaysia and Taiwan because the survey involved samples from only two sources and the total number of samples collected substantially agreed with the number required from each source.

Although samples were to be randomly collected from throughout a lot, we noted a case when samples were not collected from throughout the lot. In December 1973 we visited FDA's Baltimore district office and observed the collection of a 9-can sample from a Taiwanese lot of 150 cases of sliced pineapple with at least 5 different can codes. However, nine cans, all with the same code, were collected from the nine cases on the top of the stack. Therefore, these samples were not necessarily representative of all canned pineapple in the lot. (See p. 8.)

FISCAL YEAR 1975 SURVEY NOT PLANNED

In September 1974 an FDA official said that because of limited manpower, FDA did not plan to conduct a fiscal year 1975 survey of imported canned pineapple. According to the official, canned pineapple which does not meet quality standards does not pose an imminent health hazard and FDA's limited resources could be better spent on inspecting products which do present a health hazard.

CHAPTER 4

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Although the fiscal year 1973 survey results were not projectable to all canned pineapple entering the continental United States, the survey showed that about 10 percent of the canned pineapple lots examined were below FDA quality standards. The principal sources of the substandard product were Taiwan and Malaysia. About 13 percent of the lots from these sources were substandard, and virtually all lots from other sources, including Hawaii, complied with FDA quality standards.

FDA's fiscal year 1974 survey, which was limited to Taiwan and Malaysia, showed that about 19 percent of the lots from these sources were below FDA quality standards.

Although FDA's recent surveys showed that significant amounts of canned pineapple from Taiwan and Malaysia were substandard, FDA's regulatory action has been limited to those lots included in its survey samples. As a result only substandard lots included in the survey samples were refused entry into the United States. However, it does not appear that the surveys achieved their purpose of significantly reducing entry of substandard products.

Even though canned pineapple below FDA quality standards may not pose a serious health hazard, FDA should provide for special inspection of canned pineapple imported from Taiwan and Malaysia to protect the interests of consumers as provided by the FD&C Act (see p. 1). To make the best use of its limited resources, FDA could focus on the processors most often responsible for substandard lots.

Moreover, it seems inconsistent for FDA to reject a lot when 25 percent of a sample is substandard in the same quality factor and possibly accept a lot when as much as 67 percent of a sample is substandard for a combination of quality factors. FDA should evaluate the appropriateness of accepting lots which may be substandard for a combination of quality factors.

Also, the discrepancy between the FDA headquarters analyses concerning substandard canned pineapple findings and those of the district offices indicates the need for additional training and guidance for inexperienced district office personnel who participate in such inspection activities.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary of HEW direct the Commissioner of FDA to (1) provide for special inspection of imported canned pineapple from Malaysia and Taiwan, (2) evaluate the appropriateness of accepting lots which may be substandard for a combination of quality factors, and (3) provide additional training and guidance to inexperienced district office personnel who participate in inspections to insure that quality standards are properly applied.

AGENCY COMMENTS

In a December 24, 1974, letter (see app. I), HEW told us that FDA could not conduct a special inspection of imported canned pineapple at the present time because of resource limits. HEW advised us, however, that FDA would inspect imported canned pineapple as part of its regular compliance program to identify and take corrective action against any product not complying with FDA food standards.

According to HEW, FDA consistently faces difficult choices in allocating its food inspection resources to cover a multitude of potential problems. HEW said that a special inspection of imported canned pineapple from Malaysia and Taiwan would necessitate terminating other food standards projects already underway and diverting resources from higher priority projects directed at health hazards.

HEW pointed out that FDA has intentionally committed most of its inspection resources to problems which threaten the health and safety of consumers and, therefore, fewer resources are available to address economic problems such as deceptive labeling and food standard violations which do not pose a health hazard. Nevertheless, HEW believes FDA has devoted a significant share of its resources to inspecting imported pineapple during the past 2 years.

HEW stated, however, that FDA would continue to evaluate the results of its canned pineapple survey programs for fiscal years 1973 and 1974 and on the basis of such evaluation, along with a determination of program priorities, FDA would give appropriate consideration to undertaking additional programed activity at a future date.

HEW also advised us that FDA would reevaluate its administrative guidelines to determine the appropriateness of accepting lots which may be substandard for a combination of quality factors. If any changes are necessary, FDA will issue revised guidelines.

HEW agreed that FDA should provide additional training and guidance to inexperienced district office personnel who participate in inspections to insure that quality standards are properly applied and advised us that the following steps have been taken:

--Several district office analysts have undergone special training in the examination of canned pineapple.

--FDA district offices have been provided photographs illustrating quality defects.

--Discussions have been held between Bureau of Foods' specialists and the district office personnel when analytical differences have been encountered.

CHAPTER 5

SCOPE OF REVIEW

We reviewed legislation, regulations, policies, procedures, and practices related to FDA's imported canned pineapple programs. We reviewed FDA survey guidelines and records pertaining to its 1973 and 1974 surveys of domestic and imported canned pineapple.

We interviewed FDA officials responsible for the survey activities discussed in this report. Our review was performed primarily at FDA headquarters in Rockville, Maryland, and FDA's Bureau of Foods in Washington, D.C. We visited FDA's Baltimore district office to observe the collection of an imported canned-pineapple sample and to hold discussions with district office officials.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

DEC 24 1974

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for comments on your draft report "Efforts to Exclude Substandard Canned Pineapple Imports from the United States". Our comments are enclosed.

Thank you for the opportunity to comment on this report in draft form.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED "EFFORTS TO EXCLUDE SUBSTANDARD CANNED PINEAPPLE IMPORTS FROM THE UNITED STATES

GAO RECOMMENDATION

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to provide for special inspection of imported canned pineapple from Malaysia and Taiwan.

DEPARTMENT COMMENT

The Food and Drug Administration (FDA) will continue to inspect imported canned pineapples as part of its regular compliance program to identify and take corrective action against any product that is not in compliance with food standards promulgated under section 401 of the Food, Drug, and Cosmetic Act. However, FDA cannot conduct a special inspection of imported canned pineapples at the present time because of resource limitations.

FDA consistently faces difficult choices in allocating its food inspection resources to cover a multitude of potential problems. We estimate that a special inspection of imported canned pineapple from Malaysia and Taiwan would necessitate the termination of other food standards projects already underway and diversion of resources from higher priority projects directed at health hazards. Recognizing the relative risks of various food problems, the Agency has intentionally committed most of its inspection resources to problems which threaten the health and safety of consumers. As a result, there are comparatively fewer resources available to address economic problems such as deceptive labeling and food standard violations which pose no health hazard. Even so, FDA has devoted a significant share of the resources to inspecting imported pineapple during the past two years.

Because of the above factors, we do not believe that a special inspection of imported pineapple is feasible at the present time. However, FDA will continue to evaluate

the results of the FY 73 and FY 74 programs. Based upon that evaluation, along with a determination of program priorities, the Agency will give appropriate consideration to undertaking additional programmed activity at a future date.

GAO RECOMMENDATION

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to evaluate the appropriateness of accepting lots which may be substandard for a combination of quality factors.

DEPARTMENT COMMENT

FDA will reevaluate its administrative guidelines to determine the appropriateness of combining different types of defects as discussed by the recommendation. If any changes are necessary, FDA will issue revised guidelines with a justification for the change.

GAO RECOMMENDATION

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to provide additional training and guidance to inexperienced district office personnel who participate in such inspection activities to assure quality standards are properly applied.

DEPARTMENT COMMENT

We concur with this recommendation. The following steps have already been undertaken to correct some of the analytical differences noted in the report:

. . several district analysts have undergone special training in the Bureau of Foods in the examination of canned pineapple,

. . the Bureau of Foods has sent to field offices photographs illustrating quality defects, and

. . discussions have been held between the Bureau of Foods' specialists and the districts when analytical differences have been encountered.